REMARKS

Claims 1-13 are pending in this application. Claims 1, 2, 3, 6-8, and 11-13 are currently amended.

Amendments

Amendment and/or cancellation of certain claims is in no way an admission or acquiescence to the Examiner's rejection and is not to be construed as a dedication to the public any of the subject matter of the claims as previously presented. No new subject matter has been added.

Claim 1 has been amended to clarify that the method includes "separating said biochemical component of said infectious agent from said one or more biological samples" of which support may be found throughout the originally filed specification, and at least on pages 20-21. Claims 2, 3, 6-8, and 11-13 have been amended for clarity or to correct for typographical errors. No new subject matter has been added.

Claims Rejections – 35 U.S.C. 112 – Second Paragraph

Claims 1-13 are currently rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13 stand rejected for omitting an essential step in the determination of a rate. The Examiner notes that a rate needs to be measured with at least two samples at different time points. Applicant respectfully traverses the assertion that at least two samples at different time points are necessary to determine a rate. One of skill in the art would understand that a rate may be determined by the method described in claims 1-13 from one sample at one time point and from an assumption of a baseline level of isotopic content at time zero (prior to administration of the isotope-labeled precursor molecule). This one-sample method is described for determining a rate of biopolymer synthesis, by way of example only, in U.S. Patent 5,338,686 (col. 5, lines 61-68 to col. 6 lines 1-24), which is incorporated by reference in the current application. The reference describes

that the baseline level may be estimated, using known average natural abundances of isotopes and that "minimally, a single sample of isotopically enriched biopolymer is sufficient for practicing the method of the invention," namely measuring a rate of synthesis of a biopolymer. Therefore, one of skill in the art would understand that it is possible to calculate a rate with a single sample and an estimated baseline level at time zero using the methods presently claimed, and no essential step has been omitted. Applicant respectfully requests that this basis for rejection be withdrawn.

Claims 1-13 also stand rejected for omitting the essential step of separation of the infectious agent from the host subject's sample. Claim 1 has been amended to clarify that the method comprises "separating said biochemical component of said infectious agent from said one or more biological samples" of which support may be found throughout the originally filed specification, and at least on pages 20-21. Therefore, Applicant respectfully requests that this basis for rejection be withdrawn.

Claim Rejections – 35 U.S.C. 102(b)

Hellerstein (US Patent 6,010,846)

Claims 1-13 are currently rejected under 35 U.S.C. 102(b) as being anticipated by Hellerstein (US Patent 6,010,846).

To anticipate a claim, a cited reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. Claim 1 has been amended to clarify that the method comprises "separating said biochemical component of said infectious agent from said one or more biological samples". This separating step is not explicitly nor implicitly taught in the Hellerstein (6,010,846) reference. Further, Example 6.2.5 of the Hellerstein (6,010,846) reference explicitly teaches non-separation of the biochemical component of the infectious agent from the biochemical component of the host prior to analysis by mass spectrometry. Specifically, total DNA, both viral and human, from isolated $CD4^+$ T cells were recovered using a commercial kit, hydrolyzed to free deoxyribonucleosides enzymatically, derivatized to the trimethylsilyl derivatives of deoxyribonucleosides, and injected into a table top

GC-MS instrument. At no point in this method is a separation of the HIV DNA from the human DNA suggested or required. This separating step is employed in the present claims, and provides different results and different information than the method disclosed in Hellerstein (6,010,846), namely a rate of replication or destruction of an infectious agent in a host organism. The Hellerstein (6,010,846) method provides T cell proliferation/destruction rates in an organism which may or may not encompass the rate of HIV replication or destruction in said organism. However, without the claimed separating step, the method disclosed in the Hellerstein (6,010,846) reference cannot be used to calculate the rate of HIV replication or destruction in a host organism, using the claimed methods. By way of example only and in contrast to the methods of Hellerstein (6,010,846), the present specification describes that blood is removed from the subject and the human immunodeficiency virus is isolated from the human blood plasma by ultracentrifugation. Specification of the present application at page 26, lines 28-30 to page 27, lines 1-6. Gel electrophoresis is performed to isolate viral-specific proteins, and these proteins are analyzed by mass spectrometry to determine the replication rate of the virus. Because the Hellerstein (6,010,846) reference does not teach the presently claimed step of separating, the reference is not anticipating prior art. Applicant respectfully requests that this basis for rejection be withdrawn.

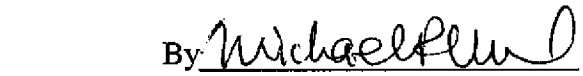
In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **416272003600**.

However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 21, 2008

Respectfully submitted,

By 

Michael R. Ward
Registration No.: 38,651

MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: (415) 268-6237
Facsimile: (415) 268-7522